MDSAP CERTIFICATE

No. 014.22-2/MDSAP

This is to certify that

GILARDONI S.P.A.

Via Arturo Gilardoni 1, 23826 Mandello del Lario (LC), Italy

Facility ID: F006604

Operates a

Quality Management System, which complies with the requirements of ISO 13485:2016 and with the requirements of the following Regulatory Authorities

Canada:
- Medical Devices Regulations – Part 1- SOR 98/282

United States:
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 - Subparts A to D
- 21 CFR Part 820

for the following scope of certification

Design, production, distribution, and servicing of medical devices for ionizing radiation treatment.

Reference to IMQ files Nos.:
DM22-0085481-01; DM23-0087875-01; DM24-0111367-01; DM26-0131706-01

Effective Date:	2026-07-16
Expiry Date:	2029-07-15
Issued on:	2026-07-13

IMQ

Matteo Raimondi – IMQ MDSAP Director

MDSAP Medical Device Single Audit Program

IMQ S.p.A. is an MDSAP Recognized Auditing Organization

This MDSAP certificate is subjected to the provisions laid down by IMQ in the "Regulation for Conformity Assessment Activities pursuant to Medical Device Single Audit Program (MDSAP) for which IMQ operates as Auditing Organization". The validity of this certificate can be verified by writing to MDSAP@imq.it.